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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,963	02/18/2004	Aldrich N.K. Lau	5118 US	1685
22896	7590	01/24/2008	EXAMINER	
MILA KASAN, PATENT DEPT. APPLIED BIOSYSTEMS 850 LINCOLN CENTRE DRIVE FOSTER CITY, CA 94404			BERTAGNA, ANGELA MARIE	
		ART UNIT		PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/780,963	LAU ET AL.
	Examiner	Art Unit
	Angela Bertagna	1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 31 October 2007.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-74 and 76-84 is/are pending in the application.

4a) Of the above claim(s) 1-20,25-44 and 50-65 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 21-24,45-49,66-74 and 76-84 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.

5) Notice of Informal Patent Application

6) Other: _____.

DETAILED ACTION

Status of the Application

1. Applicant's response filed on October 31, 2007 is acknowledged. Claims 1-74 and 76-84 are currently pending. In the response, Applicant amended claims 21, 45, and 47. Applicant's arguments and amendments have overcome all of the previous rejections, and therefore, they have been withdrawn. The following are new grounds of rejection. This Office Action is made non-final, since not all of the new rejections were necessitated by Applicant's amendment.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 21-24, 45-49, 66-72, and 76-82 are rejected under 35 U.S.C. 103(a) as being anticipated by Parthasarathy et al. (US 2003/0138779 A1; cited previously) in view of Ramstad et al. (US 2003/0228706 A1; cited previously).

The instant claims are drawn to methods of purifying PCR and DNA sequencing products using particles comprising a core for ion exchange and a polyelectrolyte coating.

Regarding claims 21 and 45, Parthasarathy teaches a method for purifying PCR reaction products or DNA sequencing reaction products, comprising:

(a) providing a plurality of particles, wherein each particle comprises an ion-exchange core coated by exposing the core to a polyelectrolyte polymer (see paragraphs 15, 42-46, and 98)

(b) contacting the PCR reaction products or DNA sequencing reaction products with the plurality of particles of step (a) to separate and purify the dsDNA fragments or dye-labeled ssDNA fragments, respectively (see paragraphs 11, 14, and 15; see also paragraphs 53-56, which teach purification of PCR products using the coated anion exchange particles and paragraphs 59-60, which teach purification of sequencing reaction products using the coated particles).

Regarding claims 22 and 46, Parthasarathy teaches that the contacting comprises moving the PCR reaction products or the DNA sequencing reaction products through the particles using centripetal force (paragraphs 74, 99, and 119).

Regarding claims 23 and 47, Parthasarathy teaches that the plurality of particles comprises a first volume and that the PCR or DNA sequencing reaction products comprise a second volume, wherein the first volume is greater than or equal to the second volume (see Example 1 on page 11 and Example 10 on page 15). In these examples, five

to ten microliters of sequencing reaction products or PCR reaction products were added to an ion exchange membrane coated with polyelectrolyte. Therefore, the volume of the added nucleic acid solutions is smaller than the volume of the membrane, and Parthasarathy teaches the limitations of claim 23.

Regarding claim 24, Parthasarathy teaches that the method of claim 21 further comprises positioning a mixture comprising the plurality of particles in a column (see paragraph 32 or paragraph 99, for example).

Regarding claim 48, Parthasarathy teaches that the method of claim 45 further comprises removing residual dye artifacts (paragraphs 11, 59, and 60).

Regarding claim 49, Parthasarathy teaches that the method of claim 45 further comprises maintaining dye-labeled ssDNA fragment length (paragraphs 59-61).

Regarding claims 66 and 76, Parthasarathy teaches coupling of the ion-exchange core with a PCR reaction product, such as dNTPs or primers (paragraphs 119-120) or a DNA sequencing reaction product, such as dye-labeled nucleotides or salts (paragraph 52).

Regarding claims 68 and 78, Parthasarathy teaches that the core comprises porous ion-exchange material (paragraph 71).

Regarding claims 69 and 79, Parthasarathy teaches that the ion-exchange material is surface-activated (paragraph 15, where coating of the ion-exchange material with polyelectrolyte results in a surface-activated particle; see also paragraphs 34-37).

Regarding claims 71, 72, 81, and 82, Parthasarathy teaches that the polyelectrolytes have a molecular weight greater than 10,000 Da (paragraph 44).

Parthasarathy does not teach providing a mixture of anionic and cationic ion-exchange particles, wherein the plurality of particles having a polyelectrolyte-coated ion exchange core are either the cationic ion exchange particles or the anionic ion exchange particles, and using the mixture of particles to purify PCR or DNA sequencing reaction products as required by claims 21 and 45. Regarding claim 47, Parthasarathy teaches that the volume of the particles is larger than the volume of added DNA sequencing reaction products (see paragraphs 98-99) rather than smaller as claimed. Finally, Parthasarathy teaches that the polyelectrolyte-coated ion exchange particles repel larger charged particles, such as PCR and DNA sequencing ladders, while binding and retaining smaller contaminants, such as salts and unextended primers (paragraph 52). However, Parthasarathy does not specify that the particles exclude dsDNA fragments having greater than 100 base pairs or ssDNA fragments that are greater than 45 nucleotides in length as required by claims 67 and 77. Parthasarathy also does not teach that the polyelectrolyte material has the claimed pore sizes and molecular weights.

Ramstad teaches methods for purifying PCR or DNA sequencing reaction products using ion exchange particles coated with a polymeric size exclusion resin (see paragraphs 20-24 and 36-37 for a general description).

Regarding claims 21 and 45, Ramstad teaches a method for purifying PCR reaction products or DNA sequencing reaction products, the method comprising:

(a) providing a plurality of particles, wherein each particle comprises a core for ion-exchange and a coating of polyelectrolyte (see paragraphs 70 & 71, where Ramstad teaches providing a plurality of particles; paragraph 20 teaches that the particles comprise an ion-exchange core with a coating of size-exclusion resin; paragraph 61 teaches that the

size-exclusion resin coating is an anionic or cationic polymer (i.e. a polyelectrolyte); see also paragraphs 53-56, where Ramstad teaches that a core for ion exchange is coated with an ion exchange resin)

(b) providing a mixture of cationic ion-exchange particles and anionic ion-exchange particles, wherein the plurality of particles of step (a) are either the cationic or anionic ion-exchange particles (see paragraphs 21 & 40)

(c) contacting the PCR reaction products or DNA sequencing reaction products with the plurality of particles of step (a) to separate dsDNA fragments or dye-labeled ssDNA fragments, respectively, and purifying the PCR or sequencing reaction products (paragraph 70 teaches purification of dsDNA fragments from a PCR; paragraph 71 teaches purification of ssDNA fragments from a sequencing reaction mixture).

Regarding claim 24, Ramstad teaches that the method of claim 21 further comprises positioning a mixture comprising the plurality of particles in a column (paragraph 21).

Regarding claim 48, Ramstad teaches that the method of claim 45 further comprises removing residual dye artifacts (paragraph 71).

Regarding claim 49, Ramstad teaches that the method of claim 45 further comprises maintaining dye-labeled ssDNA fragment length (paragraph 71).

Regarding claims 66 and 76; Ramstad teaches coupling of the ion-exchange core with a PCR reaction product, such as dNTPs or salts (paragraphs 36 and 67) or a DNA sequencing reaction product, such as dye-labeled nucleotides or salts (paragraphs 36 and 69).

Regarding claims 67 and 77, Ramstad teaches that the particle is adapted to exclude dsDNA fragments greater than 100 bp (Figure 7 and paragraph 68, where a pore size excluding 100 nt ssDNA would also inherently exclude 100 bp dsDNA) and dye-labeled ssDNA fragments greater than 45 nt (paragraph 69, where particles excluding 10 nt ssDNA would also inherently exclude 45 nt ssDNA).

Regarding claims 68 and 78, Ramstad teaches that the core comprises porous ion-exchange material (paragraphs 39, 53, and Figure 7A).

Regarding claims 69 and 79, Ramstad teaches that the ion-exchange material is surface-activated (paragraph 43).

Regarding claims 70, 72, 80, and 82, Ramstad teaches particles with an average pore size of 100 Angstroms (paragraph 56), which falls within the claimed ranges of 100-2000 Angstroms and 5-1000 Angstroms. Ramstad also teaches that the pore size range from 0-1000 Angstroms, from 100-1000 Angstroms, or 0-100 Angstroms (paragraph 53). Ramstad further teaches that the pore size can be adjusted to exclude large molecules, such as 100 nt DNA fragments or larger (paragraph 60).

Ramstad teaches that when a mixture of anionic and cationic ion exchange particles are used for the purification of a sample, counterions of the anionic and cationic ion exchange particles react to form a neutral molecule, such as water (paragraph 57). Ramstad further teaches that controlling the pore size of the polymeric material coating the ion exchange core offers the ability to combine the high selectivity and binding ability of ion exchange chromatography with size exclusion chromatography (paragraph 63).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time of invention to apply the teachings of Ramstad to the methods taught by

Parthasarathy. An ordinary practitioner of the method taught by Parthasarathy would have been motivated to purify the PCR or DNA sequencing reaction products using a mixture comprising polyelectrolyte-coated anion exchange particles and cationic ion exchange particles, since Ramstad taught that when a mixture of anionic and cationic ion exchange particles was used to purify a sample, the counterions of the anionic and cationic ion exchange particles reacted to form a neutral molecule, such as water, that did not affect down-stream processing of the sample (see paragraphs 40 and 57). Based on these teachings of Ramstad, an ordinary artisan would have recognized that using a mixture of cationic and anionic ion exchange particles to purify PCR products and DNA sequencing reaction products would have improved the purification method taught by Parthasarathy by neutralizing counterions released by the polyelectrolyte-coated anion exchange particles during the purification. An ordinary artisan also would have been motivated to apply the teachings of Ramstad regarding pore size to the method taught by Parthasarathy. Since Parthasarathy taught that the coated ion exchange particles repelled larger charged nucleic acids (*e.g.* PCR products and DNA sequencing ladders) by a combination of size and charge effects (paragraph 52), an ordinary artisan would have been motivated to optimize the pore size as suggested by Ramstad (see paragraph 60) in order to maximize the binding of small molecule contaminants and minimize the binding of PCR products or DNA sequencing ladders. Since Ramstad taught pore sizes useful for excluding DNA molecules within the claimed size ranges (see paragraphs 53, 56, & 60), an ordinary artisan would have had a reasonable expectation of success in applying these teachings of Ramstad to the method of Parthasarathy. Likewise, an ordinary artisan would have been motivated to adjust the molecular weight of the polyelectrolyte as

necessary to achieve the desired purification properties. Since polyelectrolytes within the claimed molecular weight ranges were known in the art at the time of invention, an ordinary artisan would have had a reasonable expectation of success in optimizing this results-effective variable. Finally, regarding claim 47, an ordinary artisan would have recognized that the relative volume of the particles and the DNA sequencing products was a results-effective variable that could be optimized in order to obtain the desired results (e.g. increased purification capacity). An ordinary artisan would have optimized this results-effective using routine experimentation, which as noted in MPEP 2144.05, is *prima facie* obvious. Thus, the methods of claims 21-24, 45-49, 66-72, and 76-82 are *prima facie* obvious in view of the combined teachings of Ramstad and Parthasarathy.

4. Claims 73, 74, 83, and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parthasarathy et al. (US 2003/0138779 A1; cited previously) in view of Ramstad et al. (US 2003/0228706 A1; cited previously) and further in view of Breadmore et al. (WO 03/104774 A1; cited previously).

The instant claims are drawn to the PCR and DNA sequencing product purification methods of claims 21 and 45, further wherein the polyelectrolyte coating comprises polyanions and polycations added in alternating layers.

The combined teachings of Parthasarathy and Ramstad result in the method of claims 21-24, 45-49, 66-72, and 76-82, as discussed above.

These references do not teach that the polyelectrolyte coating is comprised of alternating layers of polyanions and polycations.

Breadmore teaches a method of nucleic acid purification using silica-based extraction procedures (see pages 1-2 for a general description).

Regarding claims 73, 74, 83, and 84, Breadmore teaches increasing the yield of the purification method by modifying the silica surface with polyelectrolytes. Specifically, Breadmore teaches that the stability of the adsorbed polyelectrolyte layer can be improved by using multiple layers. Breadmore further teaches coating the silica particles with a cationic polymer followed by a second coating with an anionic polymer and repeating this process to form a multilayer (see page 13).

It would have been *prima facie* obvious for one of ordinary skill in the art to coat the ion-exchange particles taught by Parthasarathy with multiple alternating layers of polycations and polyanions, since Breadmore taught that such treatment improved the stability of the adsorbed polyelectrolyte layer (see page 13, cited above). Breadmore also taught that such modifications of silica-based resins improved purification yields (see page 13), thereby providing additional motivation for an ordinary artisan to coat the ion exchange-adapted silica particles taught by Parthasarathy with multiple alternating layers of polycations and polyanions. Since the resins taught by Breadmore were used for purification of nucleic acids, including PCR and DNA sequencing reaction products (page 2, lines 1-4), an ordinary artisan would have expected a reasonable level of success in using ion exchange-adapted silica particles coated with multiple alternating layers of polyelectrolytes in the method taught by Parthasarathy. Thus, the methods of claims 73, 74, 83, and 84 are *prima facie* obvious in view of the combined teachings of Parthasarathy, Ramstad, and Breadmore.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claim 45 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8 and 21 of copending Application No. 11/057,936 in view of Ramstad et al. (US 2003/0228706 A1; cited previously).

Claims 8 and 21 of the ‘936 application recite a method for DNA sequencing comprising contacting sequencing reaction products with particles comprising an ion exchange core and a polyelectrolyte coating, isolating the particles, and sequencing the purified sequencing products. The claims of the ‘936 application do not recite providing a mixture of cationic and anionic ion exchange particles as required by the instant claim 45. However, providing such a mixture of ion exchange particles would have been obvious in view of the teachings of Ramstad. An ordinary practitioner of the method recited in

claims 8 and 21 of the '936 application would have been motivated to purify the DNA sequencing reaction products using a mixture comprising polyelectrolyte-coated anion exchange particles and cationic ion exchange particles, since Ramstad taught that when a mixture of anionic and cationic ion exchange particles was used to purify a sample, the counterions of the anionic and cationic ion exchange particles reacted to form a neutral molecule, such as water, that did not affect down-stream processing of the sample (see paragraphs 40 and 57). Based on these teachings of Ramstad, an ordinary artisan would have recognized that using a mixture of cationic and anionic ion exchange particles to purify DNA sequencing reaction products would have improved the purification method recited in claims 8 and 21 of the '936 application by neutralizing counterions released by the polyelectrolyte-coated anion exchange particles during the purification. Thus, the instant claim 45 is *prima facie* obvious over claims 8 and 21 of the '936 application in view of Ramstad.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claim 45 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12 and 15 of copending Application No. 11/355,872 in view of Ramstad et al. (US 2003/0228706 A1; cited previously).

Claims 12 and 15 of the '872 application recite a method for DNA sequencing comprising contacting sequencing reaction products with particles comprising an ion exchange core and a polyelectrolyte coating, isolating the particles, and sequencing the purified sequencing products. The claims of the '872 application do not recite providing a

mixture of cationic and anionic ion exchange particles as required by the instant claim 45. However, providing such a mixture of ion exchange particles would have been obvious in view of the teachings of Ramstad. An ordinary practitioner of the method recited in claims 12 and 15 of the '872 application would have been motivated to purify the DNA sequencing reaction products using a mixture comprising polyelectrolyte-coated anion exchange particles and cationic ion exchange particles, since Ramstad taught that when a mixture of anionic and cationic ion exchange particles was used to purify a sample, the counterions of the anionic and cationic ion exchange particles reacted to form a neutral molecule, such as water, that did not affect down-stream processing of the sample (see paragraphs 40 and 57). Based on these teachings of Ramstad, an ordinary artisan would have recognized that using a mixture of cationic and anionic ion exchange particles to purify DNA sequencing reaction products would have improved the purification method recited in claims 12 and 15 of the '872 application by neutralizing counterions released by the polyelectrolyte-coated anion exchange particles during the purification. Thus, the instant claim 45 is *prima facie* obvious over claims 12 and 15 of the '872 application in view of Ramstad.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

8. Applicant's arguments, see page 13, filed on August 2, 2007, with respect to the rejection of claim 47 under 35 U.S.C. 112, 2nd paragraph, have been fully considered and

are persuasive. Applicant's amendment to claim 47 overcomes the rejection, and therefore, it has been withdrawn.

Applicant's arguments, see pages 13-14, filed on August 2, 2007, regarding the rejection of claims 21, 24, 45, 48, 49, 66-70, 73, 76-81, and 83 under 35 U.S.C. 102(a) and 35 U.S.C. 102(e) as being anticipated by Ramstad, have been fully considered and are persuasive. Ramstad does not teach all of the elements of the amended claims, and therefore, the rejection has been withdrawn.

Applicant's arguments, see pages 14-15, filed on August 2, 2007, regarding the rejection of claims 21, 22, 24, 45, 46, 48, 49, 66, 68, 69, 76, 78, and 79 under 35 U.S.C. 102(b) as being anticipated by Kristyanne, have been fully considered and are persuasive. This rejection has been withdrawn.

Applicant's arguments regarding the rejection of claims 21-24, 45-49, 66, 68, 69, 76, 78, and 79 under 35 U.S.C. 103(a) have been considered, but they are moot in view of the new grounds of rejection.

Applicant's indication (see page 18) that the provisional obviousness-type double patenting rejections citing co-pending applications 11/057,936 and 11/355,372 will be addressed when they have been formalized is noted. These rejections have been maintained in accordance with MPEP § 804.

Conclusion

No claims are currently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Angela Bertagna whose telephone number is 571-272-8291. The examiner can normally be reached on M-F, 7:30 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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PRIMARY EXAMINER

1/22/08